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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/478,977	01/06/2000	PETER C. BROOKS	13761-727	2450

7590

04/23/2002

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EXAMINER

HARRIS, ALANA M

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 04/23/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

09/478,977

Applicant(s)

BROOKS ET AL.

Examiner

Alana M. Harris, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4,6,10-18,20-25,27-30,32-34,36-38 and 40-64 is/are pending in the application.
- 4a) Of the above claim(s) 20-25,27-30,32-34,36-38 and 40-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,6 and 10-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 18.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Response to Arguments***

1. Claims 1-4, 6, 10-18, 20-25, 27-30, 32-34, 36-38 and 40-64 are pending.  
Claims 7-9 have been cancelled.  
Claims 6 and 11 have been amended.  
Claims 20-25, 27-30, 32-34, 36-38 and 40-64, drawn to non-elected inventions are withdrawn from examination.  
Claims 1-4 and 6, 10-18 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Priority***

3. Provisional documents 60/114,877 (filed January 6, 1999), 60/114,878 (filed January 6, 1999), 60/152,496 (filed September 2, 1999) and 60/143,534 (filed July 13, 1999) from which Applicants request priority benefit were reviewed by the Examiner. Claims 1-4, 6, 10 and 12-18 are afforded the effective filing date of January 6, 1999. None of the provisional applications simultaneously reference all three monoclonal antibodies, hence claim 11 is afforded the effective filing date of January 6, 2000. Applicants are reminded that a claim as a whole has only one effective filing date.

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***Oath/Declaration***

4. The Examiner has acknowledged Applicants' submission of a declaration as Paper number 19 received January 30, 2002 that lists the four provisional applications from which priority is requested.

***Drawings***

5. Applicants have noted the objections to the drawings and state that they will submit corrected drawings. The Examiner notes that drawings did not accompany the amendment filed December 19, 2001.

***Withdrawn Objections***

***Claim Objections***

6. The objection of claim 6 is withdrawn in light of Applicants' amendment to the claim. Claims 8 and 9 have been cancelled.

***Withdrawn Rejections***

***Claim Rejections - 35 USC § 112***

7. The rejection of claims 1-4, 6 and 10-18 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of Applicants arguments. Claims 7-9 have been cancelled.

***Claim Rejections - 35 USC § 103***

8. The rejection of claims 1-4, 6, 10 and 12-14 under 35 U.S.C. 103(a) as being unpatentable over Bellon (Analytical Biochemistry 150:188-202, 1985/ IDS reference C1) is withdrawn in view of Applicants' arguments. Claims 7 and 8 have been cancelled.

9. The rejection of claims 1-4, 6, 10, 12-14, 16 and 17 under 35 U.S.C. 103(a) as being unpatentable over Bellon (Analytical Biochemistry 150:188-202, 1985/ IDS reference C1), in view of U.S. Patent Number 5,693,762 (filed June 7, 1995) is withdrawn in light of Applicants' arguments. Claims 7 and 8 have been cancelled.

10. The rejection of claims 1-4, 6, 10, 12-14 and 18 under 35 U.S.C. 103(a) as being unpatentable over Bellon (Analytical Biochemistry 150:188-202, 1985/ IDS reference C1), in view of European Patent 0 510 949 A2 (October 28, 1992) is withdrawn in view of Applicants' arguments. Claims 7 and 8 have been cancelled.

***Maintained Rejections***

***Claim Rejections - 35 USC § 112***

11. The rejection of claim 11 under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and failing to provide an enabling disclosure without complete evidence either that the claimed biological

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materials are known and readily available to the public or complete evidence of the deposit of the biological materials is maintained.

Applicants argue that a deposit is not required. Applicants assert that "the source hybridomas for the referenced antibodies may constitute depositable material" and that "the antibodies themselves constitute nonreproductive material...". These arguments are unpersuasive.

One of ordinary skill in the art must be able to practice the claimed invention. Applicants must supply guidance and information in order for the public to implement a patented invention. Granted that this application has not been allowed the specification should provide methodology to reproduce antibodies, which are chemically and structurally identical to those to be used in the claimed invention. Applicants have noted that that the source hybridomas constitute depositable material. This rejection may be obviated if Applicants supply the deposit information of the hybridomas, which produce the three monoclonal antibodies germane to the invention. The deposit of the said hybridomas would constitute deposit of the antibodies.

12. The rejection of claims 1-4, 6 and 10-18 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the antagonists, designated monoclonal antibodies, HU177, HUIV26 and XL313 for the inhibition of angiogenesis, does not reasonably provide enablement for a host of antagonists, such as an oligonucleotide is maintained. The specification does not enable any person skilled in

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the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Claims 7-9 have been cancelled.

Applicants aver, "...that they have provided sufficient guidance an working examples to enable the claimed invention." In support of their arguments Applicants state that the specification provides examples and recite published works that teach methods that aid one of ordinary skill in the art to identify several types of antagonists utilized in the claimed method. These arguments are found unpersuasive.

While screening of libraries of potential antagonists may well be within the capabilities of a person of ordinary skill in the art this would result in a burdensome search. The specification confines its examples to three monoclonal antibodies specific to denatured collagen in order to inhibit angiogenesis. There are no examples provided in the disclosure evidencing the use of other antagonists, such as a cyclic peptide nor an oligonucleotide effective in inhibiting angiogenesis. The specification appears to present an invitation to research and discover a number of potential antagonists capable of inhibiting angiogenesis. As stated in the first action on the merits mailed October 2, 2001 Applicants' claims are not commensurate in scope with what is enabled within the specification.

It would require undue experimentation for the skilled artisan to practice this invention because there is no support in the specification for the legion of antagonists that could possibly inhibit angiogenesis.

***New Grounds of Rejection***

***Claim Rejections - 35 USC § 102***

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

14. Claim 11 is rejected under 35 U.S.C. 102(a) as being anticipated by Petitclerc et al. (Cancer Research 59:2724-2730, June 1, 1999). Petitclerc discloses a monoclonal antibody designated as Mab HU177, which is directed to denatured collagens. It is reasonable to conclude that the disclosed monoclonal antibody has the same binding specificity of Applicants' claimed antagonist.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 6:30 am to 4:00 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4315 for regular communications and (703) 308-4315 for After Final communications.




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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Alana M. Harris, Ph.D.  
April 18, 2002

  
ANTHONY C. CAPUTA  
SUPERVISORY PATENT EXAMINER  
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